

governmental investigators, and given the allegations of the generalized scheme, the States have identified a false AWP. Amgen then complains that there is no evidence of a single communication with publishers as to its AWP. However, Amgen cannot plausibly deny that it provides AWPs to publishers as the complaints allege. MC ¶ 176; NC ¶ 139. No more specificity is required.

Although Amgen rehashes its argument that “Medicare does not reimburse Epogen based on AWP,” this is simply not true. While a statutory rate exists for much of the Medicare products sold, not all Medicare reimbursement for (epogen) is based on that statutory rate structure. *See* all parts of 42 U.S.C. § 1395(rr)(b)(11)(D).

Amgen also raises a factual dispute that, given the statutory rate for some Medicare reimbursement, no other purchaser – public or private – could reasonably rely upon an AWP posted by Amgen as being a reflection of the true average wholesale price for the product. Amgen Mem. at 5. But a 12(b)(6) motion is not the place for factual disputes. Amgen’s argument boils down to the claim that even if it fraudulently posted inflated AWPs for Epogen caused over-reimbursement in the private marketplace, that private marketplace could not reasonably rely upon what the average wholesale price is because some Medicare reimbursements occurred at a statutory rate. A fact claim such as this is not appropriate in a 12(b)(6) context.

### **C. AstraZeneca**

#### **1. Review of AstraZeneca allegations**

The States allege that AstraZeneca L.P. (“AstraZeneca”) has engaged in an ongoing deliberate scheme to inflate AWP with respect to 17 of its drugs. AstraZeneca documents evidence its knowledge of the relationship between published AWPs and State reimbursement. MC ¶ 251; NC ¶ 196. And AstraZeneca acknowledged that it used AWP to maintain a spread that would allow PBMs to maintain a profit, even if this meant that patients overpaid. MC ¶¶ 255-56; NC ¶¶ 200-01. The complaints refer to internal

AstraZeneca documents and reveal marketing techniques and plans highlighting the use of inflated AWPs and the marketing of the AWP spread to physicians. MC ¶¶ 260-65; NC ¶¶ 205-10. These are not limited to Zoladex. And as part of its AWP manipulation, AstraZeneca raised the price of its AWP for Zoladex while lowering the cost to physicians, hence the price raise not be driven by cost, was motivated solely to increase the provider's spread. MC ¶¶ 261-62; NC ¶¶ 206-07.

In connection with its scheme to inflate AWPs, the DOJ investigation into AstraZeneca resulted in an indictment in 2002. The indictment alleged that AstraZeneca (i) sold Zoladex® to a New Jersey physician and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey physician with materials showing how much more profit he could make by using Zoladex® rather than its competition, Lupron®. *See* MC ¶ 269; NC ¶ 214.

## **2. The AstraZeneca-specific arguments lack merit**

### **a. Rule 9(b)**

AstraZeneca's specific argument boils down to the complaint that the allegations satisfy Rule 9(b) as to only one drug Zoladex – the only drug for which it supplied information to the government.

The purpose of Rule 9(b) is of course to put the defendant on notice of the who, what and where and this the MC and NC do. Given the use of AWPs by AstraZeneca, its publication of AWPs for each Appendix A drug, the allegation as to the general scheme, and AstraZeneca's use or misuse of AWP in specific instances, it is reasonable to infer the application of the scheme to all listed drugs, particularly since any additional information is exclusively within the possession of AstraZeneca.

Next, AstraZeneca complains that "plaintiffs do not even attempt to allege a 'fraudulent AWP' for any drug other than Zoladex." AstraZeneca Mem. at 2-3. Yet, in

compliance with the May 13, 2003 Order, the States identify fraudulent AWPs for every AstraZeneca drug in Appendix A. *See Section III.A, infra.*

#### **D. Aventis**

##### **1. The Complaints Satisfy 9(b)**

The complaints specify Aventis' provision of AWPs to publishers, MC ¶ 276; NC ¶ 221, and identify Aventis' awareness of the States' reliance on AWPs. MC ¶ 278; NC ¶ 223. Aventis was aware that others in the industry "have promoted differences in AWPs as a means to sell their products." MC ¶ 282; NC ¶ 227. Though it warned its employees that such marketing was improper, Aventis engaged in such promotions anyway. MC ¶¶ 281-85; NC ¶¶ 226-27. The MC and NC provide an example of Aventis promoting use of the "SPREAD" at seminars, boasting of the spread on a 100 mg vial of Anzemet. MC ¶ 281; NC ¶ 226. It actually provided its salespeople with a spreadsheet highlighting the spread and acknowledging winning a key account based on the spread. MC ¶¶ 282-83; NC ¶¶ 227-28. And the complaints specify that Aventis engaged in similar behavior with respect to the Gammar P IV product line. MC ¶¶ 284, 287; NC ¶¶ 228, 232.

Further, additional evidence of the phony nature of this Defendant's AWPs arises from its manipulation of its reported AWPs in late 2000 and 2001, when Aventis increased its reported AWPs for certain of the drugs identified in Appendix A across the board without any change in product or service offered. If these AWPs were real, price increases would not be uniform and would bear a relationship to some product change. At the same time of these price increases, cost to providers did not increase, further evidencing the phony nature of the AWPs. The specific drugs subject to this manipulation were Allegra, Allegra-D, Amaryl, Anzemet Tablets, Arava Tablets, Azmacort, Carafate Tablets and Suspension, DiaBeta, Intal, Lantus, Lasix, Nasacort, Nasacort AQ, Tilade, and Trental. MC ¶ 288; NC ¶ 233.

Aventis is thus simply wrong when it argues that the complaints are silent as to specifics. And thus, consistent with Rule 9(b) the States have alleged the circumstances of the fraud, and have quoted from supporting documentation to buttress the allegations. *Kuney*, 746 F. Supp. at 237.

As for DiaBeta, Lantus, Lasix and Tilade, they are not in the charts or Appendix A, so there is nothing to dismiss as they were never identified as being a drug subject to the complaint.

#### E. Baxter

##### 1. Review of Baxter allegations

Baxter claims the MC paints Baxter with broad assertions of wrongdoing, and do not “particularize” Baxter’s role.” Baxter Mem. at 1. But the MC does more than that. First, it details examples of Baxter’s control of the published price of its AWPs. MC ¶ 298. And the complaint outlines how Baxter was aware of the fact that the AWP spread was being used by others to increase market share: “The deliberate manipulation of AWP or WAC prices is a problem that we need to address....” MC ¶ 301. Nonetheless, Baxter adjusted its AWPs to meet the competition:

A recent review of industry published direct prices and AWPs revealed that Baxter’s published AWPs are significantly lower than competitive AWPs. *We have therefore adjusted our AWPs to meet competitive levels.*<sup>14</sup>

Baxter prepared marketing documents comparing for physicians the difference between AWP and their cost, so these providers could see the “return to practice” uttered by the spread.

And the MC quotes from a “Confidential — Baxter Internal use only” document confessing that “Increasing AWPs was a large part of our negotiations with the large

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<sup>14</sup> Such an adjustment solely to meet competition rebuts Baxter and other Defendants’ consistent arguments that there is no motive to compete based on AWPs in the generic or multiple-source market. And such an adjustment, without regard to price or product change, supports the complaints’ allegation that AWPs were phony and artificial numbers. MC ¶¶ 173, 177, 191.

homecare companies.” MC ¶ 306. This document places Baxter in the heart of the AWP scheme, is not limited to any specific drug, and involves PBMs. as part of the scheme

The complaints then details example of the spreads Baxter had created as part of the AWP scheme. MC ¶ 307. And in paragraph 309 the complaint sets forth sixty examples of such manipulation, by drug, the dose and the identifiable and estimated false AWP, identifying spreads that are staggering: 813%; 821%; 344%; 650%; 595%; 634%; 650%; 645%.

The complaints then provides specific examples of secret rebates given by Baxter (e.g., MC ¶ 310); and identifies additional spreads resulting from the AWP scheme regarding other Baxter drugs that are as high as 41,167% and 54,199%. MC ¶ 97.

## **2. The Baxter-specific arguments lack merit**

### **a. Lack of specificity of general allegations of the AWP Scheme**

In light of the detailed allegations summarized above, Baxter’s assertion that the complaint simply paints Baxter with broad assertions (Baxter Mem. at 1) is silly. As is its invocation that Rule 9(b) requires a party “to not file first and search for a cause of action.” The foregoing makes it clear Montana did not file first, and that it filed because it had enough evidence to implicate Baxter and has satisfied Rule 9(b). By any definition of Rule 9(b), this Defendant has notice of the claims being asserted against it.

### **b. Alleged lack of specifics to support each count**

Baxter complains that Montana does not “allege which state residents purchased any of the Baxter drugs identified.” Baxter would apparently require the State to identify in *a complaint* the names of each such resident. Such a pleading requirement would be unparalleled in the history of this nation. Attorneys General regularly bring *parens patriae* cases, but no reported case has ever required a listing of all covered residents in the complaint. Baxter cites no such authority. And indeed the courts have recognized

that, unlike a class action, the State has a more relaxed burden in pursuing claims for all injured consumers. *See* Section III.E.

Baxter's arguments as to the Best Price claims are addressed elsewhere. *See* Section III.D.

As to the False Claims Count IV, the complaint alleges that as a result of the AWP Inflation Scheme, and the Best Price scheme, Baxter made false claims by publishing phony AWPs knowing that these would be used by others seeking reimbursement from the State. MC ¶ 687. So Baxter is dead wrong when it claims the complaint does not link Baxter to a false claim.

### **3. Multiple Source Drugs Should Not Be Dismissed**

Baxter's arguments here are all addressed in Section III.C, *supra*. And, as is the case with other defendants, Baxter's own spreads belie the assertion that "a defendant cannot gain a competitive advantage by increasing the AWPs for its multi-source drugs." Compare Baxter Mem. at 4, with MC ¶ 309, outlining Baxter's enormous spreads. And Baxter's assertion is rebutted by MC ¶¶ 301-02, where Baxter discusses the need to address the "deliberate manipulation of AWP" and does so by "*adjusting our AWPs to meet competitive levels.*" MC ¶ 302. In light of this admission that AWPs were adjusted to meet competitive levels, Baxter's assertion is laughable but for the fact it is so patently false as to be sanctionable. And Baxter's assertion is rebutted by Dey's complaint against the publishers, where Dey admits that the industry competes based upon spread and that when its inflated AWPs were no longer accepted by the publishers, it immediately lost customers. ¶ 200.

## **F. Bayer**

### **1. Review of Bayer allegations**

In connection with its scheme to inflate AWPs, Bayer has been investigated by the Department of Justice, Department of Health and Human Services, Office of

Inspector General, and the Commonwealth of Massachusetts. For example, in a report published by DHHS, the DOJ documented at least 10 instances where the published AWPs for various dosages of two drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers. MC ¶ 328.

Bayer acknowledges, as it must, that Bayer was the first to settle investigations regarding inflated AWPs:

The government's investigation of the allegations ... revealed that [Bayer] beginning in the early 1990s, falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost – used by state governments to set reimbursement rates for the Medicaid program. By setting an extremely high AWP and, subsequently, selling drugs at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit tremendously from reimbursement paid to them by the government.

The Bayer AWPs at issue in the investigation involved Bayer's biologic products such as Kogenate, Koate-HP, and Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases. The investigation further revealed that the practice in which Bayer selectively engaged, commonly referred to as "marketing the spread," also had the effect of causing other drug companies to inflate their AWPs. [MC ¶ 324.]

"Bayer Corporation Settlement on Medicaid Drug Prices" (P011236-011237).

Bayer also acknowledges, as it must, that earlier this year it settled the largest-ever Medicaid fraud settlement involving its drug pricing practices for Cipro and Adalat:

Boston, MA. . . . The nation's largest-ever Medicaid fraud settlements have been reached today with two American pharmaceutical companies, BAYER CORPORATION and GLAXOSMITHKLINE. The companies have agreed to pay settlement amounts totaling more than \$344 million for their fraudulent conduct in a scheme commonly referred as "lick and stick," in which they sold re-labeled products to an HMO at deeply discounted prices, and *then concealed and avoided their obligation to pay millions of dollars in additional rebates to the Medicaid program.*

. . . BAYER CORPORATION ("Bayer") and GLAXOSMITHKLINE ("GSK"), have each agreed to

settle charges in connection with their efforts to evade paying rebates to state Medicaid programs which were based on the lowest drug prices they were offering to an HMO.

Today's agreement with BAYER calls for BAYER to pay a total of \$257,200,000 to resolve criminal charges and civil liabilities in connection with the fraudulent drug pricing of its drugs, Cipro, an antibiotic, and Adalat CC, an extended release, anti-hypertensive.

Additionally, BAYER has agreed to comply with the terms of an amended corporate integrity program designed to ensure that BAYER will accurately report its best price information to the government. [Emphasis added.]

In short, Bayer has twice been caught with its hand in the cookie jar, once in 2001 and again in 2003, all for drug pricing fraud charges. Each of those probes involved apparent drug pricing practices, and each affected the manner in which public and private purchasers paid for Bayer drugs, all on the basis of the average wholesale price.

## **2. Bayer-specific arguments**

### **a. The State has standing**

Bayer's standing argument is a bit hard to follow. It begins, after some boilerplate citations, by stating that "the complaint fails to identify a single Bayer product for which its citizens paid." Bayer Mem. at 2-3. The State alleges that it paid inflated prices for all drugs in Appendix A. MC ¶¶ 14-18, 23, 313-14. And Bayer ignores the fact that the complaint alleges that Montana citizens purchased AWP inflated drugs. MC ¶¶ 19-21. So Bayer is simply wrong. In essence, Bayer tries to import the standing requirements in the class case, to a case where the State alleges that it has purchased every drug in Exhibit A, and so have its residents.

Bayer next complains that Appendix A is defective because it simply states a fraudulent AWP. This argument has been addressed. See Section III.A-B.

Bayer next claims that the State's settlements bar this litigation. The State agrees that the 2001 agreements bar some of the State's claims as to the *drugs* in the agreement up to the time of execution of the agreement, but Mithracin and DTIC were not covered

by the agreement. Moreover, neither agreement bars *parens patriae* claims, which are not claims belonging to the State. And indeed the 2003 Agreement expressly acknowledges the State does not have authority to release claims of private payors or insurers. Bayer Ex. 2, p. 7, ¶ 4.

Further the covered conduct in the 2003 Agreement is solely Best Price conduct, not AWP inflation. *See* Ex. 2, pp. 3-4. In sum, the releases work as follows:

<u>2001 Agreement</u>	<u>2003 Agreement</u>
Does not release Nithracin or DTIC dose	Does not release Bayer on any drugs for period post agreement
Does not release <i>parens patriae</i> claims	Does not release on AWP conduct
Does not release Bayer on drugs for period post agreement	Does not release <i>parens patriae</i>

## G. Boehringer Group

### 1. Review of Boehringer Group allegations

The MC and NC allege that Boehringer Ingelheim Corporation, Ben Venue Laboratories, Inc. and Bedford Laboratories (“The Boehringer Group”) have knowingly participated and engaged in an organization-wide and deliberate scheme to artificially inflate AWPs in order to increase the market share of their products. *See* MC ¶¶ 332-46; NC ¶ 241-55. The complaints allege that The Boehringer Group has stated fraudulent AWPs for 18 of its drugs. *Id.*

The complaints specify instances in which the Boehringer group supplied AWPs to the publishers. *See, e.g.*, MC ¶ 340; NC ¶ 249. Its internal documents reveal the company was aware that spreads were of great importance to its providers. MC ¶ 342; NC ¶ 251. And the enormous spreads between reported AWP and its actual wholesale prices reveals Boehringer manipulated AWP to take advantage of the spread to increase its market share. Thus, the complaints identify, approximately 80 examples of specific estimates of the AWP spread between reported AWPs and wholesale cost. *See, e.g.*, MC

¶ 343; NC ¶ 252. As for Rule 9(b) purposes, this defendant certainly has the who, what, where and when. The amounts of the spreads created by AWP manipulation are staggering, 573%, 562%, 654%, 3,242%, 478%, 507%, 604%, 1,402%, 1337%, 1367%, 1,066%. And in ¶ 346 and ¶ 255, the complaints identify actual spreads for nine drugs, again with percentages ranging from 155% to 2495%.

## **2. Specific Arguments**

### **a. The defendants surely know which drug they manufactured**

Boehringer complains that the complaints fail to identify which Boehringer entity “was supposed to have committed the specific act.” Boehringer Mem. at 3. The complaints identify the drugs at issue and the AWPs under attack. *See, e.g.*, MC ¶¶ 332, 343, 346 and App. A; NC ¶¶ 241, 252, 255 and App. A. These defendants know which of them manufactured which drug, and have been put on notice of the drugs at issue. The State need not tell these Defendants information obviously in their possession, that is not the purpose of Rule 9(b).

### **b. Multiple-source drugs**

Boehringer claims that the May 13, 2003 Order in the Class case requires the State to specify which Medicare beneficiaries and which private health plans were deceived. Again, no case has required the States to identify in a complaint all citizens they are acting on behalf of. Boehringer cites no such case. *See* Section III.E.

### **c. Boehringer Ingelheim should be subject to discovery**

Boehringer claims that one of its subsidiaries does not engage in the manufacture of any of the drugs at issue. The Court should allow jurisdictional discovery on this issue. *See* Braun argument below, at 2(b).

## H. Braun

### 1. Review of Braun allegations

The complaints allege that Braun of America, Inc. (“Braun”) has knowingly participated and engaged in an organization-wide and deliberate scheme to artificially inflate AWPs in order to increase the market share of its products, *see MC ¶¶ 347-63; NC ¶¶ 256-72*, and that Braun has stated fraudulent AWPs for all or almost all of its drugs. MC ¶¶ 352-59; NC ¶¶ 261-68. The six specific Braun drugs for which relief is sought in the complaints are set forth in Appendix A to each.

Braun understood that a higher AWP was “advantageous with payors who reimburse based on a cost plus arrangement.” MC ¶ 353; NC ¶ 262 (citing June 15, 1992 Braun memorandum). Although Braun recognized that manipulating AWPs to meet its competitors was “scandalous,” “unethical” and “fraudulent,” Braun promptly proceeded to manipulate its AWPs and market the spread in an effort to match the competition. MC ¶¶ 354-55; NC ¶¶ 263-64.

An October of 1997 memorandum reveals that Braun subsequently performed an analysis to “assure that McGaw AWPs are in line with Baxter/Abbott AWPs on competitive products.” *See MC ¶ 357; NC ¶ 266.* Indeed, an October 17, 1997 memorandum reveals that the company increased AWPs following a review of 200 drugs to “make them equivalent to both Baxter and Abbott.” *Id.* Braun increased the AWPs of 29 drugs in 1996 for the same reason. *Id.* The DOJ has documented at least 23 instances where the published AWPs for various dosages of three drugs manufactured by Braun were substantially higher than the actual prices listed by wholesalers. MC ¶ 363; NC ¶ 272. Furthermore, its own documents reveal that Braun used free goods, educational grants and other incentives to lower the effective price of its drugs without lowering the AWP. MC ¶ 361; NC ¶ 270.

Braun's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the States of Nevada and Montana and their citizens. MC ¶ 351; NC ¶ 260.

**2. Braun-specific arguments lack merit**

**a. Braun was properly served**

Braun challenges service of process, Braun Mem. at 1 n.2, but Braun is wrong. Service is affected pursuant to the law of the State in which the District Court is located. Fed. R. Civ. P. 4(e); *Barrett v. Lombardi*, 239 F.3d 23, 26 (1st Cir. 2001). Massachusetts authorizes service by mailing, Mass. Gen. Laws Ch. 223A, § 6, and that is what was done here as confirmed by Braun in the DiNardo affidavit. Therefore, Braun was properly served.

**b. The complaints make a *prima facie* showing of personal jurisdiction but, alternatively, the Court should grant jurisdictional discovery**

The States allege that Braun, a Pennsylvania corporation, designs, manufactures and markets medical devices and certain intravenous solutions, and manufactured several drugs reimbursed by the Nevada and Montana Medicaid Programs and purchased by their citizens. NC ¶¶ 45-47; MC ¶¶ 58-60. They also allege that Braun acquired McGaw, Inc., in 1997, at which time McGaw then became "B. Braun McGaw," a wholly-owned subsidiary of Braun. NC ¶ 46; MC ¶ 59. These facts, when coupled with the weighty substantive allegations against Braun, make out a *prima facie* showing of personal jurisdiction. *See, e.g., Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A.*, 290 F.3d 42, 51 (1st Cir.), *cert. denied*, 537 U.S. 1029 (2002).

Based on the DiNardo affidavit, Braun argues that the Court does not have jurisdiction over Braun because, purportedly, Braun does not design, manufacture or sell drugs. Braun Br. at 1-2. But as Braun ignores, whether a corporate parent's connections to its subsidiary are sufficiently involved to lead to personal jurisdiction is "*highly fact-*

"*specific*" and warrants limited discovery into jurisdictional issues. *See, e.g., City of Bangor v. Citizens Communications Co.*, 2003 U.S. Dist. Lexis 16667, at \*18-25 (D. Me. Sept. 22, 2003) (emphasis added); *see also Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003) ("Although the plaintiff bears the burden of demonstrating facts that support personal jurisdiction, . . . courts are to assist the plaintiff by allowing jurisdictional discovery unless the plaintiff's claim is 'clearly frivolous.'") (citations omitted). Because Mr. DiNardo's affidavit is so intentionally oblique, it merely begs questions that must be resolved in discovery. For instance, he explains that Braun is not the successor-in-interest to McGaw merely by claiming that "McGaw was merged into a different, separate corporate entity" that goes unnamed. DiNardo Aff. at ¶ 6. Similarly, Mr. DiNardo claims that Braun does not engage in designing, manufacturing or marketing generic drugs, without explaining more like, for example, what Braun's business involves, if its activities indeed differ from those alleged in the complaints. Both of these statements, devoid of any particulars, are contrary to the allegations of the Montana and Nevada complaints. As such, they raise fact issues that should be resolved through, at a minimum, limited discovery into corporate structure and jurisdictional contacts.

**c. Nevada's complaint properly states AWP-related claims for dextrose, dextrose sodium chloride and sodium chloride**

Braun argues that Nevada's AWP claims for dextrose, dextrose sodium chloride and sodium chloride should be dismissed because Nevada has not based reimbursements for these products on published AWPs since May 2000 and that, consequently, AWP claims for these products are time barred under the three-year statute of limitations for claims sounding in fraud. Braun Br. at 3-4. As a threshold matter, Braun ignores the appropriate statutes of limitation. Under Nevada RICO, the limitations period is *five* years from the latter of when the violation occurs or when the injured person sustains the

injury, N.R.S. § 207.520, and not three years. For Nevada's Medicaid Fraud claim, the statute of limitations is *four* years from discovery. N.R.S. § 422.590.

A three year limitations period applies only to Nevada's claims under its deceptive trade practices statute, *see* N.R.S. § 11.190(3)(d), yet Braun fails to disclose that the three-year limitation period for fraud actions accrues "upon the discovery by the aggrieved party of the facts constituting fraud."<sup>15</sup> Importantly, when the plaintiff knew or in the exercise of proper diligence should have known of the facts constituting the elements of a cause of action is a question of fact for the trier of fact to decide and can be determined by the Court as a matter of law only where uncontroverted evidence proves that the plaintiff discovered or should have discovered the facts giving rise to the claim. *Siragusa v. Brown*, 971 P.2d 801, 812 (Nev. 1998) (applying civil conspiracy and Nevada RICO).

Factual issues abound here. For example, Braun references the recent Nevada Medicaid Services Manual update relating to "Department of Justice's federally-mandated pricing study." Braun Mem. at 3. This study resulted in *First Databank* making AWP changes for a handful of certain generic drugs; Nevada still reimburses at AWP less 15% for these drugs, Nevada Medicaid Manual at 1203.1D, contrary to Braun's assertion. A factual inquiry must be made to determine which Braun drugs were subject to the AWP change and for what time periods, why the change occurred, and whether Braun altered any of its unlawful activities in response. Whether any of these facts put Nevada on notice of fraud and thereby triggered the limitations period is plainly a question of fact that cannot be determined at this time. *See Siragusa*, 971 P.2d at 812; *Bemis v. Estate of Bemis*, 967 P.2d 437, 440 (Nev. 1998) (the question of when a party should have discovered a cause of action "is a question of fact to be determined by the

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<sup>15</sup> Montana also employs the discovery rule. *See, e.g., E.W. v. D.C.H.*, 754 P.2d 817, 821 (Mont. 1988); *Masse v. State Department of Highways*, 664 P.2d 890, 892 (Mont. 1983) (statutes of limitation commence to run on date of discovery of facts which would give rise to cause of action).

jury or trial court after a full hearing") (quoting *Millspaugh v. Millspaugh*, 611 P.2d 201, 203 (Nev. 1980)).

**d. Braun's challenge to Montana's AWP-based Medicaid reimbursement claims does not defeat the allegations of the complaint**

Braun asserts that Montana's AWP-based Medicaid reimbursement claims must be dismissed because Montana *may* reimburse for non-innovator, multiple-source drugs based on several options, including "direct price" and the "usual and customary charge." Braun Mem. at 4. But this argument ignores the complaint's *controlling* allegations that Montana actually reimburses for generic drugs at 150% of the lowest AWP or, if the generic drug does not have at least three suppliers, AWP less 15%. MC ¶ 188 (citing Mont. Admin. R. 37.86.1101). Thus, Montana's allegations regarding generic drug reimbursement falls squarely within the AWP Inflation Scheme engaged in by Braun for the Braun generic drugs targeted in the Montana complaint.

**e. The States' *parens patriae* claims should not be dismissed**

Braun's final challenge is to the States' *parens patriae* claims brought on behalf of the citizens of Nevada and Montana. Braun first argues that Montana cannot bring a co-payment claim for Medicaid participants who pay *flat* co-pays. Braun Mem. at 5. Braun's assertion is actually correct, and that is why Montana's complaint does not seek any recovery for these co-pays.

In a footnote, Braun asserts that the States do not have standing to bring claims on behalf of their citizens. Notably, no other defendant raised this argument despite the common nature of the issue. Failing to cite any supporting authority, Braun invokes a chimerical conflict between Attorney General authority and the private class actions. There is no conflict that prohibits the States from proceeding with *parens patriae* claims, particularly since a class is not even certified in a *parens patriae* case. *See, e.g., In re Toys "R" Us Antitrust Litig.*, 191 F.R.D. 347, 351 (E.D.N.Y. 2000) ("Rule 23 is

inapplicable to *parens patriae* actions, since the Attorneys General are specifically authorized by statute to sue."); *In re Compact Disc Minimum Advertised Price Antitrust Litig.*, 216 F.R.D. 197, 204 (D. Me. 2003) (same).<sup>16</sup>

## I. Dey

### 1. Review of Dey allegations

The six specific Dey drugs for which relief is sought in this case are set forth in Appendix A to the MC. All of these are multiple-source drugs. Dey complains that the allegations against it lack specifics.

The MC specifies instances in which Dey was directly involved in providing AWPs to the publishers and quotes from a Dey pleading that “[f]or over ten years, until April 2003, no prices other than those submitted by Dey have been listed by First Databank as AWP for Dey products . . . . MC ¶ 389. Though Dey argues it makes no sense to inflate AWPs for multiple-source drugs, and the complaint lacks specifics, its internal documents cited in the MC are to the contrary: “TO PROVIDE INCENTIVE TO RETAIL/CHAIN PROVIDERS TO USE DEY’S ALBUTEROL UD BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS.” (DL-TX-0090852) (confidential). Thus, in the pharmacy and chain distribution network, Dey “WILL INCREASE SPREAD FOR RETAIL AND PROVIDE DEY WITH HIGHEST PROFIT.” (DL-TX-0090854) (confidential).

And Dey worked with its providers to help maximize their spreads so that Dey could get the business: “This account needs AWP-40% or better to see profit due to the employer groups they serve. Have not made the switch to our product line due to the spread . . . .” (DL-TX-0014029)

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<sup>16</sup> Braun’s sole case – *Estados Unidos Mexicanos v. DeCoster*, 229 F.3d 332 (1st Cir. 2000) – does not remotely apply here because the court held that “[b]y definition, a foreign nation has no cognizable interests in our system of federalism[,] [a]nd such interests are a critical element of *parens patriae* standing.” *Id.* at 339. Of course, Nevada and Montana are not foreign governments and therefore are not under any such standing constraints.

And the MC sets forth numerous examples of the hidden spreads between AWP and wholesale acquisition costs for Dey drugs. MC ¶¶ 398, 401. In fact there are 48 specific citations that provide specificity as to the Dey drug, the dose and the AWP versus the estimated real wholesale price. *Id.* And these spreads are significant, many in the 200% to 300% range.

In June 2003, after having lost motions to dismiss and for summary judgment, Dey paid the State of Texas \$18,500,000 to settle similar charges. MC ¶ 407.

## **2. The Dey-specific allegations lack merit**

### **a. Non-innovator multiple source drugs**

Dey claims that claims with respect to non-innovator multiple source drugs should be dismissed. Dey Mem. at 1. This argument has been addressed elsewhere. *See* Section III.C.

Dey next claims that any claims involving multiple-source drugs should be dismissed because “any alleged manipulation or overstatement of AWP could not have had any effect.” This issue has also been addressed elsewhere. *See* Section III.C. The MC’s allegations also contradict Dey’s “no effect” argument. For example, the MC cites instances where Dey’s spreads were 177%, 239%, 355%, 488%. MC ¶ 408. Such spreads belie the notion that there was no incentive to manipulate. And the allegations provide examples of the incentive: for example, MC ¶ 392 explains where Dey acknowledges that one pricing strategy was to “increase the spread on Medicare/Medicaid reimbursements.” *See also* MC ¶¶ 187-81, which rebut Dey’s argument.

### **b. Rule 9(b) has been satisfied**

Dey next claims that the complaint fails to satisfy Rule 9(b). In doing so it ignores the general allegations attributable to all Defendants and quarrels with the specifics in the MC. Dey has admitted that it and virtually every drug manufacturer

participating in Medicaid programs “communicates their suggested AWP price to the reporting services.” MC ¶ 199. And Dey, in litigation against two of the publishers, has now complained that for the first time these publishers are “independently reporting an AWP different than that submitted by Dey.” MC ¶ 200. Dey then goes on to complain that with the lower AWP being reported, its provider reimbursement was reduced and hence it was losing business. *This is a tacit admission as to virtually each aspect of the State's case.* It admits that Dey had competed by marketing spread, and that when the publisher refused to use Dey’s phony AWPs, Dey immediately lost business. MC ¶ 200. These allegations rebut the notion that in the multiple-source market there is no incentive to inflate AWP. The MC then goes on to identify specific instances of Dey drugs where this manipulation has occurred. MC ¶¶ 398, 401, 408-09. These allegations certainly meet the who, what, when and where under the *Franklin v. Parke-Davis* standard.

#### c. Dey’s complaint about the “evidence” is silly

Dey complains that the excerpted pricing proposal incorporated in the MC is fabricated. Dey at 4. The excerpt is used in the MC as an example of how Dey’s own documents showed the AWP is vastly larger than the actual prices for Dey products. While the “% spread” column included in the complaint does not appear on the original document (*see* Dey, Ex. A), the *math* for the “% spread” column *is accurate*. The MC Table 1 for Dey is not “manufactured evidence.” In fact, as Dey’s own document confirms, for each of the drugs listed in the table, Dey’s representations regarding the AWP bear no relationship to wholesale acquisition costs, suggested sale prices or actual transaction price.<sup>17</sup> And Table 1 certainly sets forth the who, what, when and where by drugs and spread.

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<sup>17</sup> The MC Table 1 for Dey does not purport to be the actual version of the table as it exists in Dey’s own records. The only difference between the Table and the MC and the chart in Dey’s own document is the mathematical calculation of the spread between AWP and suggested sale price (although the original document does provide percentage spreads between WAC and sales price). There is nothing “manufactured” about the allegations in the MC.

**d. The Dey action is an admission of the scheme**

Dey closes by noting that its action against two of the publishers is irrelevant. As noted, the Dey action confirms the use of AWPs that deviate from AWP to such an extent that when Dey's AWPs were more accurately reported, "within one day . . . Dey has already been contacted by at least nine of its customers complaining about the drastic changes. . . and indicating that because of those charges, the customers would not be able to purchase Dey products since they could not earn a reasonable profit. . . ."

MC ¶ 200.

This allegation confirms not just the scheme but also the use of AWP manipulation in the generic market by Dey's competitor.

**J. GSK Group**

**1. Review of GlaxoSmithKline allegations**

In the MC the State alleges specific facts against GlaxoSmithKline, Inc. and SmithKline Beecham, PLC ("The GSK Group" or "GSK"). Specifically, the MC relies in part on several federal and state investigations revealing that The GSK Group engages in a deliberate and ongoing scheme to inflate AWP. *See* MC ¶¶ 463-64.

GSK's own documents recognize that AWPs is the benchmark for reimbursement, "Most, but not all, plans determine a payment for *new drugs*, based on the drug's cost as listed in the *Red Book* and pay all providers that amount less any patient co-payments." MC ¶ 428. This statement refers to "drugs" and is not limited to just Zofran or Kytril. Elsewhere in the same document GSK acknowledges: "Payment amounts for most payers is usually based on the AWP as listed in *Red Book*, however, co-payments, especially for Zofran Tablets will be required." *Id.*

And GSK has admitted that the marketing of its drugs is based, in part, on the spread. MC ¶ 447. This statement does not limit this practice to Zofran or Kytril.

**2. The GSK-specific arguments lack merit**

**a. The claims should not be limited to Zofran and Kytril**

GSK claims that the claims should only proceed as to Kytril and Zofran. It cites to the May 13, 2003 Order in the Class case as authority for this proposition, but as explained elsewhere the State has complied with all three requirements of the Order.

As required by *Franklin v. Parke Davis*, and *Kurney*, the MC must, under Rule 9(b), provide a general outline of the fraud, and the circumstances of the fraud, and is not required to plead every instance of fraud in a complex and far-reaching matter.

Here the circumstances of the fraud have been adequately outlined and as to GSK the inflated AWP for each drug at issue has been identified. What GSK now demands is the type of evidentiary detail set forth regarding Zofran and Kytril, but Rule 9(b) does not require such detail for every drug in the MC.

And GSK is wrong when it alleges the MC does not contain detail regarding other drugs. In ¶ 456, the MC specifically notes that in 2000 and 2001 GSK increased AWPs on 51 drugs without any change in the product or service offered. MC ¶ 456. If these AWPs were real, price increases would not have been uniform and would bear a relationship to some product change. *Id.* When all of the allegations are taken together, Rule 9(b) has been satisfied as to all GSK drugs.

**K. Immunex**

**1. Review of Immunex allegations**

Immunex is named in the NC and MC for manipulating the AWPs for five drugs. The complaints detail how Immunex controlled the published AWPs for its drugs. MC ¶ 468; NC ¶ 289.

The MC also details Immunex's knowledge that providers were making a profit based on the spread between real price and AWP: "Leucovorin and Methotextate represent significant revenue sources for the physician office or clinic due to the spread (difference between acquisition cost and AWP) physician have reaped substantial

profits.” MC ¶ 472; NC ¶ 293. And Immunex tailored its pricing to take advantage of the AWP spread. MC ¶ 473; NC 294.

In response to government subpoenas Immunex produced price lists revealing that its AWPs were inflated; thus, the MC identifies 25 specific examples of inflated AWPs, with estimated spreads of 234%, 203%, 626%, 1,026% and 1,003%.

## **2. The Immunex-specific arguments lack merit**

### **a. Multiple-source drugs**

Immunex divides the multiple source issue into two components, *parens patriae* and Medicaid. As to *parens patriae*, Immunex simply refers the court to the class case and states dismissal is warranted for the reasons set forth in its opposition to the class complaint. However, this argument glosses over a substantial difference between the cases. Much of Immunex’s argument in the class case centered on standing and the lack of a purchaser for each of its drugs. In the State cases, with the State action *parens patriae*, this issue falls away.

As to the Medicaid claims, for the reasons stated above, AWP inflation occurs in the multiple source market, and the States have explained how (MC ¶¶ 189-200; NC ¶¶ 152-63) and why (MC ¶ 475; NC ¶ 296, alleging spreads of 234%; 309%; 625%; 1026%; 1003%). In fact, the States’ citation to Immunex’s own staggering spreads contradict its arguments as to these drugs not fitting within the AWP Inflation paradigm. Even if Immunex were correct, which is disputed by the complaints’ allegations, this argument does not remove from the case non-Medicaid claims, which would consist of *parens patriae* claims for Medicare Part B co-payors and third-party payors.

### **b. Rule 9(b) is satisfied**

Immunex claims the complaints fall short of identifying the specific drugs purchased, the fraudulent AWP, and the name of plaintiff who purchased the drug.

Immunex is wrong. The complaints identify each drug purchased and lists such drugs in Appendix A. Immunex suggests that the names of citizens must be alleged. Immunex Mem. at 3. Nonsense. No authority requires a State in a *parens patriae* case to identify by name the consumers it is acting on behalf of. Indeed to do so would violate the privacy rights of those patients.

Immunex next complains that although the complaints identify the fraudulent AWPs, they do not state how they are fraudulent. The complaints state the "how" in numerous places. MC ¶¶ 176-211; NC ¶¶ 139-74.

As to Immunex's single source drugs, the complaints set forth the general scheme and identify the fraudulent AWPs on these drugs, as required by the May 13, 2000 Order. The Order did not require pleading "what the actual prices were," Immunex at 4, and these prices are in any event hidden.

The real prices are only known to Immunex, and courts do not require a complaint to allege facts not capable of being discovered.

**c. Best Price claims**

Again, the Best Price and AWP claims share a common element – that the drug companies were providing free goods, credits, discounts and other giveaways, without reflecting such in the AWP and Best Prices reported. It would be nonsensical for the companies to hide these discounts in setting AWP, but to then reveal them by reporting these in the Best Price arena. Given the detailed allegations of AWP manipulation, specific examples of huge spreads on Immunex drugs, and examples of free products to its customers (MC ¶ 476; NC ¶ 297), the States have put Immunex on notice as to the Best Price allegations.

**L. Novartis**

**1. The AWP scheme is pled with specificity**

**a. The nine drugs for which no AWP is listed in Appendix A**

Paragraph 497 of the MC and ¶ 318 of the NC state that “the specific drugs . . . for which relief is sought in this case are set forth below or in Appendix A.” The nine drugs Novartis identifies are not in Appendix A, so it’s unclear why Novartis moved to dismiss these drugs.

**b. AWP allegations as to the drugs identified in Appendix A**

The complaints identify with respect to Novartis a fraudulent AWP for each drug. When coupled with the general allegations of the industry-wide misuse of AWP, these allegations satisfy Rule 9(b). And additional evidence of the phony nature of this Defendant’s AWPs arises from its manipulation of its reported AWPs in late 2000 and 2001, when it increased its reported AWPs for certain of the drugs identified in Appendix A across the board without any change in product or service offered. MC ¶ 501; NC ¶ 322. If these AWPs were real, price increases would not be uniform and would bear a relationship to some product change. At the same time of these price increases, cost to providers did not increase, further evidencing the phony nature of the AWPs. The specific drugs subject to this manipulation were Clozaril, CombiPatch, Comtan, Diovan, Diovan HCT, Elidel, Estraderm, Exelon, Famvir, Femara, Focalin, Lamisil, Lescol/Lescol XL, Lotensin, Lotensin HCT, Miocalcin Injection & Nasal Spray, Parlodel, Rescula, Ritalin Hydrochloride, Ritalin LA, Starlix, Tegretol, Tegretol-XR, Trileptal, Vivelle/Vivelle-Dot, Voltaren Ophthalmic, Zaditor, and Zelnorm. *Id.* Given these allegations, Novartis is on notice of the how, when and why of the scheme. And for the same reasons, Nevada’s racketeering allegations provide sufficient notice, particularly where the information is largely within the control of Novartis, and Novartis has not been the subject of any discovery.

**c. Best Price allegations**

The states incorporate Section III.D. in response.

**M. Pfizer**

**1. The complaints properly allege AWP fraud as to Pfizer**

Pfizer claims that the complaints “fail to allege a fraudulent spread between AWPs and alleged secret, discounted prices.” Pfizer Mem. at 1. Elsewhere Pfizer claims that the complaints fail to clearly and concisely allege a fraudulent AWP. Pfizer, in doing so, ignores that the complaints have pages of allegations documenting an industry-wide practice of creating fraudulent AWPs that do not reflect discounts and giveaways. And the complaints “clearly and precisely” allege a fraudulent AWP by identifying that AWP in Appendix A. Nothing more needs to be stated. As to the “how or why” (Pfizer Mem. at 2), the complaints state that each AWP identified in the Appendix is inflated due to any of the above discounts, credit memos, free goods, rebates, promotions, educational grants and other inducements. Although which of these devices is used for which drug is not specified for each of Pfizer’s drugs, the complaints put Pfizer on notice that the listed AWPs do not reflect real prices. And Pfizer, having been caught by OIG engaging in Best Price fraud and paying \$49 million to settle the case, cannot be surprised by such allegations.

**2. The Best Price claims should not be dismissed**

The states have set forth the general allegations as to the Best Price scheme. With respect to Pfizer the states have identified an example where Pfizer was caught cheating on Best Price. With the specific information exclusively with Pfizer’s control, the states have satisfied Rule 9(b). Pfizer would require the State at the complaint stage to list each quarterly submission for each drug, and identify the specific Best Price on each drug that should have been provided to the States. This would turn Rule 8(a) on its head. To the extent more is required, discovery of Pfizer should be permitted pursuant to *Becher*.

**N. Pharmacia Group**

**1. Review of Pharmacia's allegations**

There is little question that the MC alleges Pharmacia's involvement in the AWP scheme. In internal documents, Pharmacia notes that at one time AWPs were the actual selling price, but that process changed in the 1980s due to competition. MC ¶ 516. This change resulted in Pharmacia marketing AWPs that differed in a "staggering" fashion with the true price. MC ¶ 522.

In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices in detail:

The manipulated disparities between your company's reported AWPs and DPs are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.  
[MC ¶ 518.]

In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

Drug	AWP	Suggested New Contract Price
Adriamycin (10 mg)	46.00	7.50
Adriamycin (50 mg)	230.00	37.50
Neosar (2 g)	86.00	18.00
Toposar (1 g)	1,330.75	120.00
Vincasar (2 mg)	741.50	7.50

(P007615). MC ¶ 520.

If that is not enough detail, the MC identifies the differences between Red Book AWP and posted AWP for many other Pharmacia drugs (MC ¶ 526):

<b>Drug</b>	<b>The Pharmacia Group's 2001 Red Book AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Spread</b>
Amphotericin B	\$36.26	\$16.00	\$20.26	127%
Bleomycin Sulfate	\$309.98 <sup>18</sup>	\$158.67	\$151.31	96%
Clindamycin Phosphate	\$93.60	\$61.20	\$32.40	53%
Cyclophosphamide	\$6.29	\$3.92	\$2.37	60%
Cytarabine	\$8.98	\$4.06	\$4.92	122%
Doxorubicin HCL	\$1104.13	\$150.86	\$953.27	632%
Etoposide	\$157.65	\$9.47	\$148.18	1,565%
Fluorouracil	\$3.20	\$1.47	\$1.73	118%
Hydrocortisone Sodium Succinate	\$2.00	\$1.55	\$.45	29%
Metholprednisolone Sodium Succinate	\$2.05	\$1.45	\$.60	41%
Testosterone Cypionate	\$17.01	\$11.79	\$5.22	44%
Vincristine Sulfate	\$43.23	\$5.10	\$38.13	748%

Additional evidence of AWP inflation by Pharmacia is in MC ¶ 522, which lists over 100 examples of AWP inflation, with estimated spreads of 249.5%, 427.9%, 956%, 667%, 661.4%, 693%, 645%, 588%, 649%.

## 2. The Pharmacia Group-specific arguments lack merit

### a. A claim has been stated with respect to Celebrex

Pharmacia spends a portion of its motion on just one of the drugs at issue, Celebrex. The gist of its argument is that as Celebrex is mentioned only a few times in the complaint, it is not enough. Like the other defendants, Pharmacia ignores the Order directing how to comply with 9(b), while Montana does so. And it ignores all of the general allegations relating to Pharmacia, the AWP Inflation Scheme, and Pharmacia's

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<sup>18</sup> Calculation based on the AWP listed in the 2000 *Red Book*.

role in marketing the spread, which is detailed in the MC. This complaint adequately alleges the general scheme, the fraudulent AWP as to Celebrex, and satisfies Rule 9(b).

**b. Multiple-source drugs should not be dismissed**

Pharmacia conflates the Best Price allegations with the AWP allegations. Its memorandum asks for dismissal of all multiple source drugs. Pharmacia begins by claiming multiple source drugs do not fit the paradigm. It then discusses these drugs solely in the context of Best Price issues and asks the Court to dismiss all “multiple source claims.” However, as for AWP-based claims, multiple source drugs clearly meet the paradigm of the AWP Inflation Scheme. *See* Section III.C. And Pharmacia’s spreads evidence why (e.g., MC ¶ 521; spreads of 828%, 252%, 521%, 2,171%). Thus, the Court certainly cannot dismiss the AWP claims.

As for Best Price claims on multiple-source drugs, this has been addressed in Section III.D. Pharmacia then claims that Montana does not specify which rebate drugs are based on AMP-11 and which are based on Best Price, and Pharmacia states that it is not its responsibility “to guess.” Pharmacia Mem. at 3. Nonsense, Pharmacia is the manufacturer that makes the drug and pays the rebate and knows which drugs have rebates based on Best Price and which do not.

**c. Montana’s Best Price allegations are adequate**

Pharmacia next argues that the MC does not satisfy the Court’s May 13 Order. Pharmacia would have the Order require the listing on a day-by-day basis, either (1) purchases at a lower price, or (2) specific sale improperly excluded from AMP. This demand is actually the equivalent of demanding that the complaint list for each drug the actual AWP, which the Court did not require. And, of course, Pharmacia knows that the information demanded is exclusively in its possession and would be impossible to calculate without discovery. This distinguishes *LaCorte v. Merck & Co., Inc.*, No. 99-3807, slip op. at 6 (E.D. La. Aug. 27, 2003), where the court refused to relax Rule 9(b)

where the specific Best Price information was not in the exclusive possession of the defendant. And the *LaCorte* case conflicts with the authorities in this district, which require an outline of the scheme to defraud and excuse a high degree of precision where the facts are peculiarly within the defendants' control. *See* Section III.B.

**O. Schering-Plough Group (Schering and Warrick)**

**1. Review of Schering-Plough allegations**

The States allege specific facts against Schering-Plough Corporation ("Schering"), which includes its wholly owned subsidiary Warrick. Specifically, the States allege, and several governmental investigations have confirmed, that Schering created and implemented a fraudulent scheme to artificially elevate prices charged for 27 specific drugs and substantially increased the sales volume and market share of those drugs at those elevated prices.

Schering Plough is the target of a criminal investigation involving: (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. MC ¶ 544; NC ¶ 345. During the investigations, the Texas Attorney General's investigators determined that Schering provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The Schering-Plough Group sold a box of albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. MC ¶ 545; NC ¶ 346.

According to Schering's own documents, the published AWPs for most of its drugs were higher than the actual prices provided to wholesalers. MC ¶ 539; NC ¶ 340. According to Warrick's own documents, Warrick consistently maintained a spread

between the AWPs and the direct prices it offered for its albuterol products. For example, a “Price Change” alert dated June 7, 1999 sent to Warrick customers provides:

Product	Pkg. Size	NDC <b>59930</b>	AWP	Direct Price
Albuterol Inhalation Aerosol	17 g	1560-1	\$21.41	\$3.40
Albuterol Aerosol Refill	17 g	1560-2	\$19.79	\$3.40

(WAR0000532) (Highly Confidential). ¶ 537. Thus, Warrick touted a 529% spread on its albuterol inhalation aerosol and a 482% spread on the refill. As a matter of fact, in response to government subpoenas, Schering produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. *Id.* These reports reveal that for albuterol inhalers, used by millions of asthmatics, the secret spreads for Warrick were 272%, 313%, 122% and 61%. MC ¶ 540; NC ¶ 341. Montana, acting in its *parens patriae* capacity, also sues on behalf of consumers and payors of all types. With respect to sales to PBMs, the spreads it was creating were even higher: 2,082%, 757%, 460% and 533%. MC ¶ 540; NC ¶ 341.

## 2. The Schering Plough/Warrick-specific arguments lack merit

### a. Purported State knowledge

This issue is addressed in the consolidated brief, is not a “specific defense,” and is therefore not properly in Schering’s “Defendant-specific” brief, and is an attempt to avoid the page limits of the Court’s Order. The states have responded to this argument in the Consolidated Memorandum at Section II.D, and in this memorandum at Section III.E. As noted in Section III.E., introduction, this argument has no application to the States’ *parens patriae* claims. As to those claims, the allegations of the MC affirmatively state that Defendants concealed price discounts (MC ¶ 636), instructed providers and others not to report price (MC ¶ 637), concealed the fact of AWP inflation and of AWP manipulation (MC ¶ 640). Defendants of course have gone outside the record in attempting to defeat the fraudulent concealment allegations as to the States, but have put

nothing in the record documenting knowledge by consumers or third-party payors. As to the States, in addition to the arguments represented in the consolidated memorandum, Schering cites a 1990 study, indicating that AWP overstated prices by 10-20%. This actually is consistent with the States' lack of knowledge. The States recognize some variance existed between published AWP and real AWP and therefore reimburses at AWP-15%. Knowledge of a small discount — and even that is a fact issue — does not put the States on notice that Schering was out marketing spreads of 2,082%, 757%, and 460%, and that the company was providing free goods to providers whose value was not included in determining the AWP. MC ¶ 544.

**b. The complaints meet Rule 9(b)**

Schering's argument is the same made by at least sixteen of the Defendants, to wit: that the complaints must do more than set forth general allegations, plus specify the fraudulent AWP at issue. However, and again, the States followed the Court's May 13 Order. The complaints have a purchaser for each drug, the States and residents, and have identified the fraudulent AWPs at issue. The States have provided an outline of the scheme as required by authorities in this district (see Section III.A.) and have provided some degree of precision and substantiation as to each Defendant.

**c. Best Prices**

The complaints also allege how, in parallel fashion with the AWP Inflation Scheme, Defendants also fail to report discounts and price reducing inducements when reporting Best Price. This general scheme, coupled with the identification of an AWP, coupled with allegations as to the use of free samples by each defendant, is sufficient.

*See Section III.D.*

**P. TAP Pharmaceutical**

**1. Review of TAP Pharmaceutical allegations**

TAP's egregious track record regarding its inflation of AWPs is well known. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. MC ¶ 583.

At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

*United States v. TAP Pharm. Prods., Inc.*, No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001); MC ¶ 584.

TAP's manipulation does not end here. In addition to marketing the spread, TAP has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. For example, TAP has pled guilty to illegally conspiring with medical providers to provide free samples, which would then be billed, to Medicare. In an October 3, 2001, press release that referenced the guilty plea, TAP's president, Thomas Watkins, stated:

We admit that TAP provided free samples of Lupron to a number of physicians, primarily in the early to mid-1990s, with the knowledge that those physicians would seek and receive reimbursement. The billing for free samples is wrong, and it should never have happened. [MC ¶ 577.]

TAP has also provided and/or arranged for many other non-public financial inducements to stimulate the sales of its drugs at the expense of the Montana Medicaid

Program and Montana citizens. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. MC ¶ 578. All of these incentives are designed to lower the cost of the drug to the medical provider while concealing the actual cost from the State.

**2. The TAP Pharmaceuticals-specific arguments lack merit**

TAP misconstrues what is required by Rule 9(b) and the May 13, 2003 Order. The State is not required to allege a “spread.”

What the State is required to do under 9(b) is to allege the general scheme, which the State has done by identifying the corporate climate and industry with respect to AWP manipulation practices. And the State has buttressed those allegations by detailing the corporate climate at TAP with respect to AWP manipulation (MC ¶ 582-88) and has specified the AWPs at issue in Appendix A.<sup>19</sup> That is precisely what the May 13 Order required.

TAP now poses an additional requirement that the State identify competitors for the brand name drugs at issue. The Court did not require this in the May 13 order, nor should it. The State would then have to identify competitors for all of Defendants’ drugs, and there is no case suggesting that 9(b) would impose such a requirement. In any event, TAP knows well who its competitors are.

Plaintiffs respectfully submit that the remaining TAP arguments have been addressed elsewhere.

**Q. WARRICK**

**1. The Complaints State Claims for Multiple Source Drugs**

Warrick repeats the same arguments previously made as to generic drugs, and the States have responded. See Section III.C., and discussions in many of the previous 16 briefs. Warrick adds no new argument.

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<sup>19</sup> The States identify AWPs for Prevacid for 1998, 1999 and 2001.

Warrick does claim that the State has not identified a single Warrick drug in the private sector whose reimbursement is based on AWP. However, the complaints detail how in the private sector AWP is the benchmark for reimbursement in the private sector. MC ¶¶ 165-166, 193-195. And the complaints specify that even if MAC is the basis, ultimately the reimbursement is tied to AWP. MC ¶ 194. So the complaints tie generic drugs to AWP.

## 2. The Complaints Satisfy 9(b)

Warrick recycles the same tired and bankrupt arguments made by every Defendant challenging the complaints' particularity for failing to allege spreads. Warrick at 3-5. The States respectfully refer the Court to Section III.A-B, *supra*, for rebuttal.

Warrick also challenges the invoicing pricing set forth in some of the examples contained in the complaints. Warrick at 3-5. However, Warrick overlooks that the complaints mirror data contained in Warrick's *own* documents. Furthermore, the tables cited in the complaints do not purport to be precise spread calculations and are intended only as barometers of spread abuse. As Warrick well knows, precise spread calculations must await the production of information, including average sales prices, that is under the exclusive control of Warrick. Nonetheless, there is nothing "vague" or "contrary" about the very large spreads exemplified in the complaints and taken from Warrick's own documents.

Warrick also asserts that the State fails to allege the prices it paid for Warrick drugs, Warrick at 4, but as discussed above, this goes to damages and need not be pled. Nor did the Court require it in its May 13 Order.

Finally, Warrick raises a 9(b) challenge to the States' Best Price allegations. Warrick at 5. This has been addressed *supra* at Section III.D.

## V. CONCLUSION

The States of Montana and Nevada ask that the Court deny the motions to dismiss.

By/s/ Signature on file with Court

DATED: October 10, 2003.

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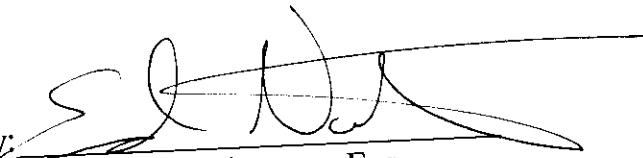
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**CERTIFICATE OF SERVICE**

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copy of the foregoing State of Montana's and State of Nevada's Memorandum in Opposition to Defendant-Specific Memoranda on Motions to Dismiss to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2 on this 10<sup>th</sup> day of October, 2003.

By:

  
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